US-PAT-NO: 6361545

DOCUMENT-IDENTIFIER: US 6361545 B1

TITLE: Perfusion filter catheter

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Abstract Text - ABTX (1):
A perfusion filter catheter is used to capture potential emboli within the aorta during heart surgery and cardiopulmonary bypass. An expandable embolic filter assembly having fine filter mesh for capturing macroemboli and microemboli is mounted on a catheter shaft having a perfusion lumen with perfusion ports located upstream of the filter. The embolic filter assembly can be actively or passively deployed within the ascending aortic. An optional outer **tube** covers the embolic filter assembly to prevent premature deployment. Radiopaque markers, sonoreflective markers and/or an aortic transillumination system are provided to monitor the position of the catheter and the deployment state of the embolic filter assembly. The embolic filter assembly is configured to maximize the effective filter surface area when deployed. Embolic filter assembly configurations described include an elongated cone, a frustum of a cone, a trumpet-shape, a modified trumpet-shape, and helically, circumferentially and longitudinally convoluted shapes, as well as configurations having standoff members for centering the filter and holding the filter mesh away from the aortic walls when deployed. Oxygenated blood is perfused through the perfusion lumen and any embolic materials that might be dislodged are captured in the deployed embolic filter assembly. Embodiments are also described that combine the perfusion filter catheter with an aortic occlusion device, which may be a toroidal balloon, an expandable balloon or a selectively deployable external catheter flow control valve. The combined device allows percutaneous transluminal administration of cardiopulmonary bypass and cardioplegic arrest with protection from undesirable embolic events.

Application Filing Date - AD (1):
19980922

Brief Summary Text - BSTX (11):
In keeping with the foregoing discussion, the present invention takes the form of a perfusion filter catheter or cannula having an embolic filter assembly mounted on an elongated **tubular** catheter shaft. The elongated **tubular** catheter shaft is adapted for introduction into a patient's ascending aorta either by a peripheral arterial approach or by a direct aortic puncture. A fine filter mesh for capturing macroemboli and/or microemboli is mounted on the embolic filter assembly. The embolic filter assembly has an undeployed state in which the filter is compressed or wrapped tightly around the catheter shaft and a deployed state in which the embolic filter assembly expands to the size

of the aortic lumen and seals against the inner wall of the aorta. The embolic filter assembly can be passively or actively deployable. Various mechanisms are disclosed for both passive and active deployment of the embolic filter assembly. Optionally, an outer **tube** may cover the embolic filter assembly when it is in the undeployed state. Radiopaque markers and/or sonoreflective markers, may be located on the catheter and/or the embolic filter assembly. Preferably, a perfusion lumen extends through the elongated **tubular** catheter shaft to one or more perfusion ports upstream of the embolic filter assembly. Oxygenated blood is perfused through the perfusion lumen and any embolic materials that might be dislodged are captured in the deployed embolic filter assembly.

Drawing Description Text - DRTX (21):

FIGS. 42 and 43 show another alternate embodiment of a perfusion filter catheter with an actively deployed embolic filter assembly having a filter support structure with a preshaped, superelastic wire purse string **loop**.

Detailed Description Text - DETX (3):

Referring now to FIG. 1, the perfusion filter catheter 100 includes an elongated **tubular** catheter shaft 104 with a proximal end 108 and distal end 110. The catheter shaft 104 is preferably extruded of a flexible thermoplastic material or a thermoplastic elastomer. Suitable materials for the catheter shaft 104 include, but are not limited to, polyvinylchloride, polyurethane, polyethylene, polypropylene, polyamides (nylons), and alloys or copolymers thereof, as well as braided, coiled or counterwound wire or filament reinforced composites. The **tubular** catheter shaft 104 may have a single lumen or multilumen construction. In the exemplary embodiment shown, the catheter 100 has a single perfusion lumen 106 extending from the proximal end 108 to the distal end 110 of the catheter shaft 104. The perfusion lumen 106 is open at the distal end 110 of the catheter shaft 104. The distal end 110 of the catheter shaft 104 may have a simple beveled or rounded distal edge, as shown, or it may include additional side ports or a flow diffuser to reduce jetting when oxygenated blood is infused through the perfusion lumen 106. The proximal end 108 of the elongated **tubular** catheter shaft 104 is adapted for connecting the perfusion lumen 106 to a cardiopulmonary bypass pump or other source of oxygenated blood using standard barb connectors or other connectors, such as a standard luer fitting (not shown). Preferably, the catheter shaft 104 is made with thin walled construction to maximize the internal diameter and therefore the flow rate of the perfusion lumen 106 for a given outside diameter and length of the catheter shaft 104. Thin walled construction also allows the outside diameter of the catheter shaft 104 to be minimized in order to reduce the invasiveness of the procedure and to reduce trauma at the insertion site. The perfusion lumen 106 should be configured to allow sufficient blood flow to preserve organ function without hemolysis or other damage to the blood. For standard cardiopulmonary support techniques, a catheter shaft 104 of 18-24 French size (6-8 mm outside diameter) is sufficient to deliver the requisite 3-4 liters of oxygenated blood to preserve organ function. For low flow cardiopulmonary support techniques, such as described in commonly owned, copending patent application Ser. No. 60/084,835, filed May 8, 1998 which is hereby incorporated by reference, the size of the catheter shaft 104 can be

reduced to 9-18 French size (3-6 mm outside diameter) for delivering 0.5-3 liters of oxygenated blood to preserve organ function. The catheter shaft 104 should have a length sufficient to reach from the arterial access point where it is inserted to the ascending aorta of the patient. For femoral artery deployment, the catheter shaft 104 preferably has a length from approximately 80-120 cm.

Detailed Description Text - DETX (7):

The embolic filter assembly 102 may be deployed by a passive means or by an active means. Passive means for deploying the embolic filter assembly 102 could include using the elastic memory of the filter screen 112 and/or the filter support structure 114 to deploy the embolic filter assembly 102, and/or using pressure from the blood flow in the aorta to deploy the embolic filter assembly 102. By contrast, active means for deploying the embolic filter assembly 102 could include one or more actuation members within the catheter shaft 104 for mechanically actuating the filter support structure 114 to deploy the embolic filter assembly 102 from the proximal end 108 of the catheter 100. Shape memory materials may also be used as actuation members for deploying the embolic filter assembly 102. Alternatively, active means for deploying the embolic filter assembly 102 could include one or more lumens within the catheter shaft 104 for hydraulically actuating the filter support structure 114 to deploy the embolic filter assembly 102. Passive means may be used to augment the action of the active deployment means. As shown in FIG. 3, an outer **tube** 124 may be provided to cover the embolic filter assembly 102 when it is in the collapsed state in order to create a smooth outer surface for insertion and withdrawal of the catheter 100 and to prevent premature deployment of the embolic filter assembly 102, particularly if passive deployment means are used.

Detailed Description Text - DETX (8):

The perfusion filter catheter 100 is prepared for use by folding or compressing the embolic filter assembly 102 into a collapsed state within the outer **tube** 124, as shown in FIG. 3. The distal end 110 of the catheter 100 is inserted into the aorta in a retrograde fashion. Preferably, this is done through a peripheral arterial access, such as the femoral artery or subclavian artery, using the Seldinger technique or an arterial cutdown. Alternatively, the catheter 100 may be introduced directly through an incision into the descending aorta after the aorta has been surgically exposed. The embolic filter assembly 102 is advanced up the descending aorta and across the aortic arch while in the collapsed state. The position of the catheter 100 may be monitored using fluoroscopy or ultrasound, such as transesophageal echography (TEE). Appropriate markers, which may include radiopaque markers and/or sonoreflective markers, may be located on the distal end 110 of the catheter 100 and/or the embolic filter assembly 102 to enhance imaging and to show the position of the catheter 100 and the deployment state of the embolic filter assembly 102. When the distal end 110 of the catheter 100 is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the outer **tube** 124 is withdrawn and the embolic filter assembly 102 is deployed, as shown in FIG. 3. Optionally, a distal portion of the catheter shaft 104 may be precurved to match the curvature of the aortic arch to aid in placement and

stabilization of the catheter 100 and the embolic filter assembly 102 within the aorta. Once the embolic filter assembly 102 is deployed, oxygenated blood may be infused through the perfusion lumen 106 to augment cardiac output of the beating heart or to establish cardiopulmonary bypass so that the heart can be arrested. Any potential emboli are captured by the filter screen 112 and prevented from entering the neurovasculature or other branches downstream. After use, the embolic filter assembly 102 is returned to the collapsed position and the catheter 100 is withdrawn from the patient.

Detailed Description Text - DETX (10):

Deployment of the embolic filter assembly 102 can be accomplished passively or actively. FIGS. 4-11 show various methods of passively deploying the embolic filter assembly 102 and FIGS. 12-23 show various methods of actively deploying the embolic filter assembly 102. FIGS. 4-6 show one method of passively deploying the embolic filter assembly 102. In this exemplary embodiment, the outer hoop 116 and the struts 118 of the filter support structure 114 are made of an elastic or superelastic metal or polymer, for example a superelastic nickel/titanium alloy, which is easily deformed into the collapsed state and which expands passively from the collapsed state to the deployed state. To place the embolic filter assembly 102 in the collapsed position shown in FIG. 4, the struts 118 are folded back in the proximal direction and the outer hoop 116 is folded against the catheter shaft 104 along with the material of the filter screen 112. The outer **tube** 124 is placed over the folded embolic filter assembly 102 to hold it in the collapsed position. Once the perfusion filter catheter 100 is in position within the patient's aorta, the outer **tube** 124 is pulled back, as shown in FIG. 5, to release the folded embolic filter assembly 102. The outer hoop 116 and struts 118 expand the filter screen 112 to its deployed position, shown in FIG. 6, and hold the open distal end 122 of the filter screen 112 against the inner wall of the aorta, as shown in FIG. 1. After use, the embolic filter assembly 102 is returned to the collapsed position by advancing the outer **tube** 124 distally over the filter screen 112 and the filter support structure 114, then the catheter 100 is withdrawn from the patient.

Detailed Description Text - DETX (12):

The embolic filter assembly 132 is folded into the collapsed position shown in FIG. 7 by folding the struts 136 in the distal direction so they lie against the catheter shaft 134. FIG. 7A is a cutaway view of the catheter 130 with the embolic filter assembly 132 in the collapsed position. The material of the filter screen 140 is folded around or in between the struts 136. The outer **tube** 148 is placed over the folded embolic filter assembly 132 to hold it in the collapsed position. Once the perfusion filter catheter 130 is in position within the patient's aorta, the outer **tube** 148 is pulled back, as shown in FIG. 8, to release the folded embolic filter assembly 132. Blood flow within the aorta catches the skirt 142 of the filter screen 140 and forces the embolic filter assembly 132 to open into the deployed position shown in FIG. 8. FIG. 8A is a cutaway view of the catheter 130 with the embolic filter assembly 132 in the deployed position. Optionally, the struts 136 may be resiliently biased toward the deployed position to assist in passive deployment of the embolic filter assembly 132. As the embolic filter assembly 132 is passively opened by

the blood flow, the skirt 142 of the filter screen 140 naturally and atraumatically seals against the aortic wall. The passive deployment of the skirt 142 also naturally compensates for patient-to-patient variations in aortic luminal diameter. The filter pocket 144 of the embolic filter assembly 132 is held away from the aortic walls and away from the ostia of the side branches so that blood can flow freely through the pores of the filter screen 140.

Detailed Description Text - DETX (14):

The perfusion filter catheter 150 is shown in FIG. 9 with the embolic filter assembly 152 compressed into the collapsed position. The embolic filter assembly 152 compresses in diameter smoothly without folding as the resilient wires or filaments 156 and the fibers of the filter screen 154 decrease their angle with respect to the longitudinal axis of the embolic filter assembly 152. An outer **tube** 164 holds the embolic filter assembly 152 in the collapsed position. Once the perfusion filter catheter 150 is in position within the patient's aorta, the outer **tube** 164 is pulled back, which allows the embolic filter assembly 152 to expand, as shown in FIG. 10. As the embolic filter assembly 152 expands, the angle between the wires or filaments 156 and the longitudinal axis of the embolic filter assembly 152 increases and the embolic filter assembly 152 foreshortens slightly. FIG. 11 shows the embolic filter assembly 152 fully expanded in the deployed position. The resilient wires or filaments 156 are preformed so that, when deployed, the filter screen 154 has a roughly conical shape with an open distal end 160. The conical shape holds the filter screen 154 away from the aortic walls and away from the ostia of the side branches so that blood can flow freely through the pores of the filter screen 154. The distal end 160 of the embolic filter assembly 152 seals against the aortic wall. The self-expanding aspect of the embolic filter assembly 152 naturally compensates for patient-to-patient variations in aortic luminal diameter.

Detailed Description Text - DETX (17):

The perfusion filter catheter 166 is shown in FIG. 12 with the embolic filter assembly 168 compressed into the collapsed position. The actuation wires 174 are withdrawn into the actuation wire lumens 186 through the side ports 188 and the outer hoop 172 is folded or collapsed against the catheter shaft 184. The material of the filter screen 180 is folded or collapsed around the catheter shaft 184. An outer **tube** 190 covers the embolic filter assembly 168 in the collapsed position to facilitate insertion of the catheter 166. Once the perfusion filter catheter 150 is in position within the patient's aorta, the outer **tube** 190 is pulled back to expose the embolic filter assembly 152. Then, the actuation wires 174 are advanced distally to expand the outer hoop 172 and the filter screen 180, as shown in FIG. 13. FIG. 14 shows the embolic filter assembly 168 fully expanded in the deployed position. In this exemplary embodiment, the filter screen 180 is configured as a frustum of a cone with an open distal end 176. The outer hoop 172 at the distal end 176 of the filter screen 180 seals against the aortic wall.

Detailed Description Text - DETX (18):

FIGS. 15-17 show another method of actively deploying an embolic filter assembly 202 on a perfusion filter catheter 200. In this embodiment, the filter support structure 204 includes an outer hoop 206 and a plurality of struts 208, which are all interconnected hollow **tubular** members. Preferably, the outer hoop 206 and the struts 208 are made of a flexible polymeric material. The filter support structure 204 is connected to an inflation lumen 210, which parallels the perfusion lumen 218 within the catheter shaft 212. At its proximal end, the inflation lumen 210 branches off from the catheter shaft 212 to a side arm 214 with a luer fitting 216 for connecting to a syringe or other inflation device. By way of example, this embodiment of the embolic filter assembly 202 is shown with a trumpet-shaped filter screen 220. The filter screen 220 includes a skirt portion 222 extending distally from a proximal, filter pocket 224. The skirt portion 222 is in the shape of a frustum of a cone with an open distal end, which is attached to the outer hoop 206. The filter pocket 224 is roughly cylindrical in shape with a closed proximal end, which is sealingly attached to the catheter shaft 212. The skirt 222 and the filter pocket 224 may be made of the same filter material or they may be made of different filter materials having different porosities. The skirt 222 of the filter screen 220 may even be made of a nonporous material.

Detailed Description Text - DETX (19):

The perfusion filter catheter 200 is shown in FIG. 17 with the embolic filter assembly 202 folded into a collapsed position. The outer hoop 206 and the struts 208 of the filter support structure 204 are deflated and the material of the filter screen 220 is folded or collapsed around the catheter shaft 212. An outer **tube** 226 covers the embolic filter assembly 202 in the collapsed position to facilitate insertion of the catheter 200. Optionally, the outer **tube** 226 may have a slit or a weakened longitudinal tear line along its length to facilitate removal of the outer **tube** 226 over the side arm 214 at the proximal end of the catheter 200. Once the perfusion filter catheter 200 is in position within the patient's aorta, the outer **tube** 226 is pulled back to expose the embolic filter assembly 202. Then, the embolic filter assembly 202 is deployed by inflating the outer hoop 206 and the struts 208 with fluid injected through the inflation lumen 210 to actively expand the filter support structure 204, as shown in FIG. 16. When the embolic filter assembly 202 is deployed, the outer hoop 206 of the filter support structure 204 seals against the inner wall of the aorta, as shown in FIG. 15. Preferably, at least the outer wall of the outer hoop 206 is somewhat compliant when inflated in order to compensate for patient-to-patient variations in aortic luminal diameter.

Detailed Description Text - DETX (21):

The embolic filter assembly 232 is folded into the collapsed position shown in FIG. 20 by extending and **rotating** the inner catheter shaft 240 in a first direction with respect to the outer catheter shaft 250. This collapses the filter support structure 234 back against the inner catheter shaft 240 and furls the filter screen 244 around the inner catheter shaft 240. The spiral flutes 248 in the filter screen 244 help it to collapse smoothly around the inner catheter shaft 240. An outer **tube** 252 covers the embolic filter assembly 232 in the collapsed position to facilitate insertion of the catheter 230. Once the perfusion filter catheter 230 is in position within the patient's

aorta, the outer **tube** 252 is pulled back to expose the embolic filter assembly 232. Then, the embolic filter assembly 232 is deployed by **rotating** the inner catheter shaft 240 in the opposite direction with respect to the outer catheter shaft 250 and allowing it to retract slightly, as shown in FIG. 19. The filter support structure 234 and the filter screen 244 will expand within the aorta and the distal end 242 of the filter screen 244 will seal against the aortic wall, as shown in FIG. 18. When it is in the deployed position, the spiral flutes 248 of the embolic filter assembly 232 hold most of the filter screen 244 away from the aortic walls and away from the ostia of the side branches so that blood can flow freely through the pores of the filter screen 244. After use, the embolic filter assembly 232 is returned to the collapsed position as described above and the catheter 230 is withdrawn from the patient.

Detailed Description Text - DETX (24):

The embolic filter assembly 262 is folded into the collapsed position shown in FIG. 23 by extending the inner catheter shaft 270 distally with respect to the outer catheter shaft 280. This collapses the filter support structure 264 back against the inner catheter shaft 270 and collapses the circumferential pleats 248 of the filter screen 274 against the inner catheter shaft 270. An outer **tube** 282 covers the embolic filter assembly 262 in the collapsed position to facilitate insertion of the catheter 260. Once the perfusion filter catheter 260 is in position within the patient's aorta, the outer **tube** 282 is pulled back to expose the embolic filter assembly 262. Then, the embolic filter assembly 262 is deployed by retracting the inner catheter shaft 270 proximally with respect to the outer catheter shaft 280, as shown in FIG. 22. The filter support structure 264 and the filter screen 274 will expand within the aorta and the distal end 272 of the filter screen 274 will seal against the aortic wall, as shown in FIG. 21. When it is in the deployed position, the circumferential pleats 278 of the embolic filter assembly 262 hold the majority of the filter screen 274 away from the aortic walls and away from the ostia of the side branches so that blood can flow freely through the pores of the filter screen 274. After use, the embolic filter assembly 262 is returned to the collapsed position as described above and the catheter 260 is withdrawn from the patient.

Detailed Description Text - DETX (26):

Active deployment of the embolic filter assembly can also be accomplished with any of the preceding embodiments by using shape memory materials, such as a nickel/titanium alloy, to construct the filter support structure and/or the actuation members. The transition temperature of the shape memory material should be chosen to be close to normal body temperature so that extreme temperature variations will not be necessary for deployment. The shape memory material of the filter support structure should be annealed in the deployed position to confer a shape memory in this configuration. Then, the embolic filter assembly should be cooled below the transition temperature of the shape memory material, so that the filter support structure is malleable and can be shaped into a collapsed position. Depending on the transition temperature, this can be done at room temperature or in iced saline solution. If desired, an outer **tube** can be placed over the embolic filter assembly to facilitate catheter insertion and to avoid premature deployment. Once the perfusion

filter catheter is in position within the patient's aorta, the outer **tube** is pulled back to expose the embolic filter assembly and the filter support structure is heated above the transition temperature to deploy the embolic filter assembly. Depending on the transition temperature of the shape memory material, the filter support structure can be passively heated by body heat (accounting, of course, for decreased body temperature during hypothermic cardiopulmonary support methods) or it can be self-heated by applying an electrical current through the filter support structure. When heated, the filter support structure expands to its annealed configuration within the aorta. After use, the embolic filter assembly is returned to the collapsed position by advancing the outer **tube** distally over the filter screen and the filter support structure, then the catheter is withdrawn from the patient.

Detailed Description Text - DETX (28):

FIG. 24 shows a perfusion filter catheter 290 which is adapted for retrograde deployment via subclavian artery access. In this exemplary embodiment, the perfusion filter catheter 290 is depicted with a trumpet-style, passively-deployed embolic filter assembly 292. Because it is intended for subclavian artery access, the perfusion filter catheter 290 has a **tubular** catheter shaft 294 with a length of approximately 60-90 cm. Because of the shorter length, as compared to the femoral version of the catheter, the outside diameter of the catheter shaft 294 can be reduced to 12-18 French size (4-6 mm outside diameter) for delivering the 3-4 liters of oxygenated blood needed to preserve organ function. The reduced diameter of the catheter shaft 294 is especially advantageous for subclavian artery delivery of the catheter 290. To further reduce the size of the catheter system for subclavian or femoral artery delivery, the outer **tube** 296 may be adapted for use as an introducer **sheath** by the addition of an optional hemostasis valve 298 at the proximal end of the outer **tube** 296. This eliminates the need for a separate introducer **sheath** for introducing the catheter 290 into the circulatory system.

Detailed Description Text - DETX (29):

In use, the perfusion filter catheter 290 is introduced into the subclavian artery with the embolic filter assembly 292 in a collapsed state within the outer **tube** 296, using the Seldinger technique or an arterial cutdown. The embolic filter assembly 292 is advanced across the aortic arch while in the collapsed state. The position of the catheter 292 may be monitored using fluoroscopy or ultrasound, such as transesophageal echography (TEE). Radiopaque markers and/or sonoreflective markers, may be located on the catheter 290 and/or the embolic filter assembly 292 to enhance imaging and to show the position of the catheter 290 and the deployment state of the embolic filter assembly 292. When the distal end of the catheter 290 is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the outer **tube** 296 is withdrawn and the embolic filter assembly 292 is either actively or passively deployed, as shown in FIG. 24. Once the embolic filter assembly 292 is deployed, oxygenated blood may be infused into the aorta through the **tubular** catheter shaft 294. Any potential emboli are captured by the embolic filter assembly 292 and prevented from entering the neurovasculature or other branches downstream. After use, the embolic filter assembly 292 is returned to the collapsed position and the catheter 290 is

withdrawn from the patient.

Detailed Description Text - DETX (31):

FIGS. 25-27 show a perfusion filter catheter 300 which is adapted for antegrade deployment via direct aortic puncture. In this exemplary embodiment, the perfusion filter catheter 300 is depicted with a hybrid-style embolic filter assembly 302, which is a compromise between the conical filter screen and the trumpet-style filter screen previously described. Because the catheter 300 is introduced directly into the ascending aorta, the catheter shaft 304 can be reduced to a length of approximately 20-60 cm and an outside diameter of approximately 12-18 French size (4-6 mm outside diameter) for delivering the 3-4 liters of oxygenated blood needed to preserve organ function during cardiopulmonary bypass. An important modification that must be made to the catheter 300 for antegrade deployment is that the perfusion port or ports 306 which connect to the perfusion lumen 308 must exit the catheter shaft 304 proximal to the filter screen 310 so that fluid flow will come from the upstream side of the embolic filter assembly 302. The catheter shaft 304 need not extend all the way to the distal end of the filter screen 310. The filter screen 310 may be entirely supported by the filter support structure 312, particularly if the embolic filter assembly 302 is to be passively deployed. Alternatively, a small diameter filter support member 314 may extend from the catheter shaft 304 to the distal end of the filter screen 310. If the embolic filter assembly 302 is intended to be actively deployed, the filter support member 314 may be slidably and/or rotatably received within the catheter shaft 304. Either of these configurations allows the embolic filter assembly 302 to be folded or compressed to a size as small as the diameter of the catheter shaft 304 to facilitate insertion of the catheter 300. Optionally, an outer **tube** 316 may be placed over the folded embolic filter assembly 302 to hold it in the collapsed position.

Detailed Description Text - DETX (32):

In use, the ascending aorta of the patient is surgically exposed, using open-chest or minimally invasive surgical techniques. A purse string suture 318 is placed in the ascending aorta and an aortotomy incision is made through the aortic wall. The catheter 300, with the embolic filter assembly 302 in the collapsed position within the outer **tube** 316, is inserted through the aortotomy and advanced antegrade into the aortic arch. When the proximal end of the embolic filter assembly 302 is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the outer **tube** 316 is withdrawn and the embolic filter assembly 302 is either actively or passively deployed, as shown in FIG. 25. Once the embolic filter assembly 302 is deployed, oxygenated blood may be infused into the aorta through the **tubular** catheter shaft 304. Any potential emboli are captured by the embolic filter assembly 302 and prevented from entering the neurovasculature or other branches downstream. After use, the embolic filter assembly 302 is returned to the collapsed position, the catheter 300 is withdrawn from the patient, and the purse string suture 318 is tightened to close the aortotomy.

Detailed Description Text - DETX (36):

In use, the perfuision filter catheter 320 is introduced into the aorta with the embolic filter assembly 322 in a collapsed state within an outer **tube** 334, using one of the methods described above. The embolic filter assembly 322 is advanced across the aortic arch while in the collapsed state. When the upstream end 336 of the catheter 320 is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the outer **tube** 334 is withdrawn and the embolic filter assembly 322 is either actively or passively deployed, as shown in FIG. 29. Preferably, the embolic filter assembly 292 is dimensioned so that when it is deployed, the upstream end 330 of the filter screen 324 is positioned in the vicinity of the ostia for the brachiocephalic artery and the left common carotid artery and the downstream end 332 of the filter screen 324 is positioned downstream of this position, preferably in the descending aorta. This configuration assures that all of the perfusate which is destined for the neurovasculature must pass through the finer, upstream end 330 of the filter screen 324 to remove all microemboli and macroemboli. Whereas, the perfusate which is destined for the viscera and the lower limbs, which are more tolerant of small emboli, need only pass through the downstream end 332 of the filter screen 324, so as to remove at least the macroemboli.

Detailed Description Text - DETX (44):

The perfusion filter catheter 460 is prepared for use by bending the outer hoop 470 in the proximal direction or wrapping it around the catheter shaft 468, then folding or wrapping the material of the filter screen 464 around the catheter shaft 468. An outer **tube** 484 is placed over the embolic filter assembly 462 to hold it in the collapsed position, as shown in FIG. 37. The catheter 460 is introduced and the embolic filter assembly 462 is advanced across the aortic arch while in the collapsed state. When the distal end 474 of the embolic filter assembly 462 is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the outer **tube** 484 is withdrawn and the resilient outer hoop 470 expands to deploy the embolic filter assembly 462, as shown in FIG. 36. The outer hoop 470 and the distal end 474 of the filter screen 464 will seal against the aortic wall. After use, the embolic filter assembly 462 is returned to the collapsed position by advancing the outer **tube** 484 distally over the filter screen 464 and the filter support structure 466, then the catheter 460 is withdrawn from the patient.

Detailed Description Text - DETX (45):

FIGS. 38-41 show an alternate embodiment of a perfusion filter catheter 490 with an actively deployed embolic filter assembly 492. The embolic filter assembly 492 has a filter screen 494 with a sewn **tubular** channel 496 which extends circumferentially around the open distal end 498 of the filter screen 494. The distal end 498 of the filter screen 494 is attached on one side to the catheter shaft 504, and the proximal end 506 of the filter screen 494 is sealingly attached to the catheter shaft 504. The filter screen 494 may be configured as a conical, trumpet or other style of filter screen. The filter support structure in this embodiment consists of a preshaped, superelastic actuation wire 500, which, when the embolic filter assembly 492 is in the collapsed state, resides in a second lumen 502 within the catheter shaft 504. Preferably, the actuation wire 500 has a bead or small **loop** 508 at its distal end to create a blunt, non-piercing tip. The second lumen 502 of the catheter

shaft 504 communicates with the **tubular** channel 496 at the distal end 498 of the filter screen 494. When the actuation wire 500 is extended, it forms a hoop as it passes through the **tubular** channel 496 of the filter screen 494.

Detailed Description Text - DETX (47):

The perfusion filter catheter 490 is prepared for use by withdrawing the actuation wire 500 into the second lumen 502, then folding or wrapping the flexible material of the filter screen 494 around the catheter shaft 504. Optionally, an outer **tube** 514 may be placed over the embolic filter assembly 492 to hold it in the collapsed position, as shown in FIG. 38. The catheter 490 is introduced and the embolic filter assembly 492 is advanced across the aortic arch while in the collapsed state. When the distal end 498 of the embolic filter assembly 492 is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the outer **tube** 514 is withdrawn, which allows the filter screen 494 to unwrap from the catheter shaft 504, as shown in FIG. 39.

Detailed Description Text - DETX (48):

Then, the preshaped, superelastic actuation wire 500 is advanced distally so that it begins to form a hoop as it passes through the **tubular** channel 496 at the distal end 498 of the filter screen 494, as shown in FIG. 40. The actuation wire 500 is further advanced until it forms a complete hoop, as shown in FIG. 41, thereby sealing the distal end 498 of the filter screen 494 against the aortic wall. After use, the embolic filter assembly 492 is returned to the collapsed position as described above, then the catheter 490 is withdrawn from the patient.

Detailed Description Text - DETX (49):

FIGS. 42 and 43 show another alternate embodiment of a perfusion filter catheter 520 with an actively deployed embolic filter assembly 522. The embolic filter assembly 522 has a filter screen 524 with a sewn **tubular** channel 526 which extends circumferentially around the open distal end 528 of the filter screen 524. The distal end 528 of the filter screen 524 is attached on one side to the catheter shaft 534, and the proximal end 536 of the filter screen 524 is sealingly attached to the catheter shaft 534. The filter screen 524 may be configured as a conical, trumpet or other style of filter screen. The filter support structure in this embodiment consists of a preshaped, elastic or superelastic wire **loop** 530. The wire **loop** 530 passes through the **tubular** channel 526 at the distal end 528 of the filter screen 524. When the embolic filter assembly 522 is in the collapsed position, the wire **loop** 530 is withdrawn into a second lumen 532 within the catheter shaft 534, as shown in FIG. 42. In the collapsed position, the wire **loop** 530 acts as a purse string to close the filter screen 524 tightly around the catheter shaft 534. When the wire **loop** 530 is advanced distally, it forms a hoop that holds the distal end 528 of the filter screen 524 open, as shown in FIG. 43.

Detailed Description Text - DETX (51):

The perfusion filter catheter 520 is prepared for use by withdrawing the

wire **loop** 530 into the second lumen 532, then folding or wrapping the flexible material of the filter screen 524 around the catheter shaft 534. Optionally, an outer **tube** 538 may be placed over the embolic filter assembly 522 to hold it in the collapsed position. The catheter 520 is introduced and the embolic filter assembly 522 is advanced across the aortic arch while in the collapsed state. When the distal end 528 of the embolic filter assembly 522 is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the outer **tube** 538 is withdrawn, and the preshaped, superelastic wire **loop** 530 is advanced distally so that it forms a hoop that holds the distal end 528 of the filter screen 524 open and seals against the aortic wall. The inherent adjustability of the wire **loop** 530 used to deploy the embolic filter assembly 522 naturally compensates for patient-to-patient variations in aortic luminal diameter. After use, the embolic filter assembly 522 is returned to the collapsed position by withdrawing the wire **loop** 530 into the second lumen 532. This closes the filter screen 524 like a purse string to capture any potential emboli that are in the embolic filter assembly 522. Then, the catheter 520 is withdrawn from the patient.

Detailed Description Text - DETX (53):

The perfusion filter catheter 550 is prepared for use by deflating the toroidal balloon 560, then folding or wrapping the deflated toroidal balloon 560 and the filter screen 554 around the catheter shaft 564. Optionally, an outer **tube** 564 may be placed over the embolic filter assembly 552 to hold it in the collapsed position, as shown in FIG. 44. The catheter 550 is introduced and the embolic filter assembly 552 is advanced across the aortic arch while in the collapsed state. When the distal end 558 of the embolic filter assembly 552 is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the outer **tube** 564 is pulled back to expose the embolic filter assembly 552. Then, the embolic filter assembly 202 is deployed by inflating the toroidal balloon 560 with fluid injected through the inflation lumen 562, as shown in FIG. 45. When the embolic filter assembly 552 is deployed, the toroidal balloon 560 seals against the inner wall of the aorta. Preferably, at least the outer wall of the toroidal balloon 560 is somewhat compliant when inflated in order to compensate for patient-to-patient variations in aortic luminal diameter. After use, the toroidal balloon 560 is deflated and the catheter 550 is withdrawn from the patient.

Detailed Description Text - DETX (59):

FIGS. 46-50 show the operation of an embodiment of a perfusion filter catheter 600 that combines an embolic filter assembly 602 with a toroidal balloon aortic occlusion device 604. The embolic filter assembly 602 and the toroidal balloon aortic occlusion device 604 are mounted on an elongated catheter shaft 606 that may be adapted for peripheral introduction via the femoral artery or subclavian artery or for central insertion directly into the ascending aorta. The toroidal balloon aortic occlusion device 604 is connected to an inflation lumen within the elongated catheter shaft 606. A cardioplegia lumen, which may also serve as a **guidewire** lumen, connects to a cardioplegia port 608 at the distal end of the catheter shaft 606. A perfusion lumen connects to one or more perfusion ports 610 located on the catheter shaft 606 downstream from the toroidal balloon aortic occlusion device 604, but upstream

of the embolic filter assembly 602.

Detailed Description Text - DETX (62):
FIG. 51 shows an embodiment of a perfusion filter catheter 620 that combines an embolic filter assembly 622 with an inflatable balloon aortic occlusion device 624. The embolic filter assembly 622 may be any one of the actively or passively deployed embolic filter assemblies described herein. Preferably, the inflatable balloon aortic occlusion device 624 is an elastomeric balloon of sufficient inflated diameter to occlude the ascending aorta and is mounted on the elongated catheter shaft 626 upstream of the embolic filter assembly 622. Alternatively, the inflatable balloon aortic occlusion device 624 may be positioned to occlude the inlet end of the embolic filter assembly 622 to minimize the area of contact between the perfusion filter catheter 620 and the aortic wall. The inflatable balloon aortic occlusion device 624 is connected to an inflation lumen within the elongated catheter shaft 626. A cardioplegia lumen, which may also serve as a **guidewire** lumen, connects to a cardioplegia port 628 at the distal end of the catheter shaft 626. A perfusion lumen connects to one or more perfusion ports 630 located on the catheter shaft 626 downstream from the inflatable balloon aortic occlusion device 624, but upstream of the embolic filter assembly 622. The operation of the perfusion filter catheter 620 of FIG. 51 is quite similar to that described for the embodiment of FIGS. 46-50.

Detailed Description Text - DETX (63):
FIG. 52 shows an embodiment of a perfusion filter catheter 640 that combines an embolic filter assembly 642 with a selectively deployable external catheter flow control valve 644. The embolic filter assembly 642 may be any one of the actively or passively deployed embolic filter assemblies described herein. The selectively deployable external catheter flow control valve 644 is mounted on the elongated catheter shaft 646 upstream of the embolic filter assembly 642. Alternatively, the selectively deployable external catheter flow control valve 644 may be positioned to occlude the inlet end of the embolic filter assembly 642 to minimize the area of contact between the perfusion filter catheter 640 and the aortic wall. Selectively deployable external catheter flow control valves suitable for this application are described in commonly owned, copending U.S. patent applications Ser. Nos. 08/665,635, 08/664,361 and 08/664,360, filed Jun. 17, 1996, which are hereby incorporated by reference in their entirety. The elongated catheter shaft 646 may include one or more deployment lumens as needed for actuating the external catheter flow control valve 644. A cardioplegia lumen, which may also serve as a **guidewire** lumen, connects to a cardioplegia port 648 at the distal end of the catheter shaft 646. A perfusion lumen connects to one or more perfusion ports 650 located on the catheter shaft 646 downstream from the external catheter flow control valve 644, but upstream of the embolic filter assembly 622. The operation of the perfusion filter catheter 640 of FIG. 52 is quite similar to that described for the embodiment of FIGS. 46-50.

Current US Original Classification - CCOR (1):
606/200